

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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**PCT**

REC'D 22 OCT 2004

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## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) <b>19 OCT 2004</b>	
Applicant's or agent's file reference <b>PRO/028 PCT</b>	
<b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No. <b>PCT/IL04/00528</b>	International filing date (day/month/year) <b>17 June 2004 (17.06.2004)</b>
Priority date (day/month/year) <b>17 June 2003 (17.06.2003)</b>	
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): A61K 39/395, 38/16, 48/00 and US Cl.: 424/133.1, 134.1, 135.1, 143.1; 514/2, 44</b>	
Applicant <b>PROCHON BIOTECH LTD.</b>	

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☒ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Ron Schwadron, Ph.D. <i>J. Roberts for</i> Telephone No. 571-272-1600
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

112/0040/00528

**Box No. 1 Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ in written format

☒ in computer readable form

c. time of filing/furnishing

☒ contained in international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

II2/0040/00528

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 6

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 6 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 6 depends on a claim that does not precede it and also does not exist.

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
112/0040/00528

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>13</u>	YES
	Claims <u>1-5, 7-12, 14-26</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-5, 7-12</u>	NO
Industrial applicability (IA)	Claims <u>1-5, 7-12</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 1-5, 7-12, and 14-26 lack novelty under PCT Article 33(2) as being anticipated by WO 02/102973. WO 02/102973 discloses use of antibody or antibody fragment against FGR3 to treat psoriasis wherein psoriasis is defined in claim 12 as an autoimmune disease encompassed by claim 1 (see claim 29 and pages 6-9). WO 02/10293 discloses the antibodies/antibody fragments recited in the claims (see Table 1a and pages 17-22). The intended use for the medicament preparation recited in the claims carries no patentable weight.

Claims 1-5, and 7-12 lack an inventive step under PCT Article 33(3) as being obvious over WO 02/102973 in view of Baecklund et al.

WO 02/102973 discloses use of antibody or antibody fragment against FGR3 to treat psoriasis wherein psoriasis is defined in claim 12 as an autoimmune disease encompassed by claim 1 (see claim 29 and pages 6-9). WO 02/10293 discloses the antibodies/antibody fragments recited in the claims (see Table 1a and pages 17-22). The intended use for the medicament preparation recited in the claims carries no patentable weight. WO 02/102973 discloses that the claimed method can be used to treat lymphoma (see page 29). WO 02/102973 does not teach treatment of RA. Baecklund et al. disclose that RA patients frequently develop lymphoma. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because WO 02/102973 discloses that the claimed method can be used to treat lymphoma and Baecklund et al. disclose that RA patients frequently develop lymphoma. Therefore, the claimed method would have been used to treat lymphoma positive RA patients.

Claims 1-5, and 7-12 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.